

INFORMATION DISCLOSURE STATEMENT BY APPLICANT JUL 24 2006 (Use as many sheets as necessary)		<i>Complete if Known</i>	
		Application Number	10/811,130
		Filing Date	03/26/2004
		First Named Inventor	DEVARAJAN et al.
		Art Unit	1653
		Examiner Name	
Sheet 1	of 1	Attorney Docket Number	CHM-015

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)				

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ² -Number ⁴ -Kind Code ⁵ (if known)					

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T ²
CF		BLASER, J. et al., A Sandwich Enzyme Immunoassay for the Determination of Neutrophil Lipocalin in Body Fluids, <i>Clinica Chimica Acta</i> , 235 (1995) pp. 137-145	
		MATTHAEUS, T. et al., Co-Regulation of Neutrophil Gelatinase-Associated Lipocalin and Matrix Metalloproteinase-9 in the Postischemic Rat Kidney, <i>Pathophysiology of Renal</i>, A4112, SU1-0348 (PS).	Abstract
CF		MATTHAEUS, T., et al., Acute Ischemic Renal Failure Induces Expression of Neutrophil Gelatinase-Associated Lipocalin and Matrix Metalloproteinase-9 in Damaged Tubuli, <i>Kidney Blood Press Res</i> (2001), Vol. 24, Congress of Nephrology 2001, p 342	Abstract
CF		OHLSSON, S., et al., Increased Circulating Levels of Proteinase 3 in Patients with Anti-Neutrophilic Cytoplasmic Autoantibodies-Associated Systemic Vasculitis in Remission, <i>Clin Exp Immunol</i> (2003), Vol. 131 pp. 528-535	

Examiner Signature	<i>CF</i>	Date Considered	5/17/07
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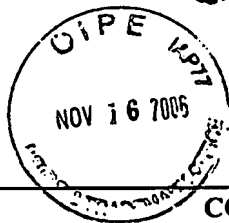
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) NOV 16 2006 Sheet 1 of 1				<i>Complete if Known</i>	
				Application Number	10/811,130
				Filing Date	03/26/2004
				First Named Inventor	DEVARAJAN et al.
				Art Unit	1641
				Examiner Name	FOSTER, CHRISTINE E
				Attorney Docket Number	CHM-015

U.S. PATENT DOCUMENTS						
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		Number	Kind Code ² (if known)			
ck		US-	5,945,294	08-31-1999	Frank et al.	
ck		US-	6,221,625	04-24-2001	Ashihara et al.	
ck		US-	6,664,385	12-16-2003	Sanicola-Nadel et al.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
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ck		Biomarkers Definitions Working Group, Biomarkers and Surrogate Endpoints: Preferred Definitions and Conceptual Framework, <i>Clinical Pharm. & Therapeutics</i> , vol. 69, No.3, March 2001, P. 89-95.	
ck		Definition for term "ELISA", www.thefreedictionary.com (1 page), 2/28/2006	
ck		DEVARAJAN, P, Novel biomarkers for the early prediction of acute kidney injury; <i>Cancer Therapy</i> (2005); Vol. 3, pp. 477-488 pages 477-485 and 487	
ck		ELNEIHOUM, A.M., et al., Leukocyte activation in atherosclerosis; correlation with risk factors, <i>Atherosclerosis</i> , 1997 May; 131(1): 79-84	Abstract
ck		HRUBEC et al, Plasma Versus Serum: Specific Differences in Biochemical Analyte Values" <i>Journal of Avian medicine and Surgery</i> 16(2):101-105,2002	
ck		KRAMER, A. A., et al.; Renal ischemia/reperfusion leads to macrophage-mediated increase in pulmonary vascular permeability; <i>Kidney International</i> (1999), Vol. 55; pp. 2362-2367	
ck		Medline Plus Medical Encyclopedia, "Serum Hemoglobin", www.nlm.nih.gov/medlineplus/ency/article/003677.htm , 3/1/2006	
ck		RABB, H., et al., Acute renal failure leads to dysregulation of lung salt and water channels; <i>Kidney International</i> (2003); Vol. 63; pp. 600-606	
ck		SCHMIDT-OTT, K. M., et al.; Neutrophil gelatinase-associated lipocalin-mediated iron traffic in kidney epithelia; <i>Current Opinion in Nephrology and Hypertension</i> (2006); Vol. 15:000-000 pp. 1-8	

Examiner Signature	<i>CFoster</i>	Date Considered	5/18/07
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Attorney Docket No. CHM-015

COPENDING U.S. PATENT APPLICATION				
Examiner Initials*	Applicant(s)	Serial No.	Filing Date	Atty. Docket No.
OK	BARASCH, et al.	11/374,285	10/13/2005	CHM-032

Examiner Signature	Date Considered
<i>Christie</i>	5/18/07



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Application Number	10/811,130
Filing Date	03/26/2004
First Named Inventor	Prasad Devarajan
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Examiner Name	
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)				
CK		US-	4,632,901	12/30/1986	Valkers et al. VALKERS et al.	
CK		US-	4,870,007	09/26/1989	Smith-Lewis	
CK		US-	5,273,743	12/28/1993	Ahlem et al.	
CK		US-	5,656,503	08/12/1997	May et al.	
CK		US-	6,500,627	12/31/2002	O'Connor et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T ³
CK		Muramatsu, Y., Tsujie, M., Kohda, Y., Pham, B., Perantoni, A.O., Zhao, H., Jo, S-K, Yuen, PST, Craig, L., Hu, X., Star, R.A. Early detection of cysteine rich protein 61 (CYR61, CCN1) in urine following renal ischemic reperfusion injury. Kidney Int., 62: 1601-1610, 2002.	
CK		Yoshida, T., Kurella, M., Beato, F., Min, H., Ingelfinger, J.R., Stears, R.L., Swinford, R.D., Gullans, S.R., Tang, S-S. Monitoring changes in gene expression in renal ischemia-reperfusion in the art. Kidney Int., 61: 1646-1654, 2002.	
CK		Supavekin, S., Zhanh, W., Kucheralapati, R., Kaskel, F.J., Moore, L.C., Devarajan, P. Differential gene expression following early renal ischemia-reperfusion. Kidney Int., 63: 1714-1724, 2003.	
CK		Nogae, S., Miyazaki, M., Kobayasji, N., Siato, T., Abe, K., Saito, H., Nakane, P.K., Nakanishi, Y., Koji, T. Induction of apoptosis in ischemia-reperfusion model of mouse kidney: Possible involvement of Fas. J. Am. Soc. Nephrol., 9: 620-631, 1998.	
CK		Daemen, MARC, Van de Ven MWCM, Heineman, E., Buurman, W.A. Involvement of endogenous interleukin-10 and tumor necrosis factor- α in renal ischemia-reperfusion injury. Transplantation, 67: 792-800, 1999.	
CK		Kelly, K.J., Plotkin, Z., Dagher, P.C., Guanosine supplementation reduces apoptosis and protects renal function in the setting of ischemic injury. J. Clin. Invest., 108: 1291-1298, 2001.	
CK		Burne, N.J., Rabb, H. Pathophysiological contributions of fucosyltransferases in renal ischemia reperfusion injury. J. Immunol., 169: 2648-2652, 2002.	
CK		Feldenberg, L.R., Thevananther, S., del Rio, M., DeLeon, M., Devarajan, P. Partial ATP deletion induces Fas- and caspase-mediated apoptosis in MDCK cells. Am. J. Physiol., 276 (Renal physiol 45): F837-F846, 1999.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

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Examiner Name	
Attorney Docket Number	CHM-015

Sheet	2	of	2
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✓	Devarajan, P., DeLeon, M., Talasazan, F., Schoenfeld, A.R., Davidowitz, E.J., Burk, R.D. The von Hippel-Lindau gene product inhibits renal cell apoptosis via Bcl-2-dependent pathways. J. Biol. Chem., 276: 40599-40605, 2001.	
✓	Yang, J., Goetz, D., Li, J-Y, Wand, W., Mori, K., Setlik, D., Du, T., Erdjument-Bromage, H., Tempst, P., Strong, R., Barasch, J. An iron delivery pathway mediated by a lipocalin. Mol. Cell., 10: 1045-1056, 2002.	
✓	Molitoris, B.A., Weinberg, J.M., Venkatachalam, M.A., Zager, R.A., Nath, K.A., Goligorsky, M.S. Acute renal failure II. Experimental models of acute renal failure: imperfect but indispensable. Am. J. Physiol. Renal Physiol., 278:F1-F12, 2000.	
✓	Kjeldsen, L., Cowland, J.B., Borregaard, N. Human neutrophil gelatinase-associated lipocalin and homologous proteins in rat and mouse. Biochim. Biophys. Acta, 1482: 272-283, 2000.	
✓	Kjeldsen, L., et al. Characterization of two ELISAs for NGAL, a newly described lipocalin in human neutrophils. J. of Immunological Methods, 198: 155-16, 1996.	
✓	Megyesi, J., Safirstein, R.L., Price, P.M. Induction of p21WAF1/CIP/SD1 in kidney tubule cells affects the course of cisplatin-induced acute renal failure. J. Clin. Invest., 101: 777-782, 1998.	
✓	Shiraishi, F., Curtis, L.M., Truong, L., Poss, K., Visner, G.A., Madsen, K., Nick, H.S., Agarwal, A. Heme oxygenase-1 gene ablation or expression modulates cisplatin-induced renal tubular apoptosis. Am. J. Physiol., 278: F726-F736, 2000.	
✓	Ramesh, G., Reeves, W.B. TNF- α mediates chemokine and cytokine expression and renal injury in cisplatin nephrotoxicity. J. Clin. Invest., 110: 835-842, 2002.	
✓	Mishra, J., Ma, Q., Prada, A., Mitsnefes, M., Zahedi, K., Yang, J., Barasch, J., Deverajan, P. Identification of NGAL as a novel urinary biomarker for ischemic injury. J. Am. Soc. Nephrol., 14: 2534-2543, 2003.	
✓	Tsuruya, K., Ninomiya, T., Tokumoto, M., Hirakawa, M., Masutani, K., Taniguchi, M., Fukuda, K., Kanai, H., Kishihara, K., Hirakata, H., Iida, M. Direct involvement of the receptor-mediated apoptotic pathways in cisplatin-induced renal tubular cell death. Kidney Int., 63: 72-82, 2003.	
✓	Bundgaard, J., Sengelov, H., Borregaard, N., Kjeldsen, L. Molecular cloning and expression of a cDNA encoding Ngai: a lipocalin expressed in human neutrophils. Biochem. Biophys. Res. Commun., 202: 1468-1475, 1994.	
✓	Del Rio, M., Imam, A., DeLeon, M., Gomez, G., Mishra, J., Ma, Q., Parikh, S., Devarajan, P. The death domain of kidney ankyrin interacts with Fas and promotes Fas-mediated cell death in renal epithelia. J. Am. Soc. Nephrol., 15: 41-51, 2004.	

Examiner Signature		Date Considered	5/18/07
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

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Application Number	10/811,130
Filing Date	03/26/2004
First Named Inventor	DEVARAJAN et al.
Art Unit	1653
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Attorney Docket Number	CHM-015

U.S. PATENT DOCUMENTS

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CF		US- 5,627,034	05/06/1997	Gould et al.	
CF		US- 5,814,462	09/29/1998	Weinberger	
CF		US- 6,136,526	10/24/2000	Venge	
		US- 6,447,989	09/10/2002	Comper	
CF		US- 6,461,827	10/08/2002	Oda et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.¹	Foreign Patent Document Country Code³-Number⁴-Kind Code⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Ts
CF		WO 01/55210	08/02/2001	Munin Corporation		
CF		WO 03/068054	08/21/2003	The Government of the United States of America as represented by The Secretary, Department of Health Services		
		WO 2004/005340	01/15/2004	Metagen Pharmaceuticals GMBH		
CF		WO 2004/005544	01/15/2004	Novartis AG		
CF		WO 2005/024054	03/17/2005	Royal Women's Hospital		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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CF		BAILLY, V., et al., Shedding of Kidney Injury Molecule-1, a Putative Adhesion Protein Involved in Renal Regeneration; The Journal of Biological Chemistry, Vol. 277, No. 42, Issue of October 18, pp. 39739-39748, 2002	
CF		CARLSON, M., et al., Human neutrophil lipocalin is a unique marker of neutrophil inflammation in ulcerative colitis and proctitis, Gut 2002; 50:501-506	
CF		EICHLER, I., Human neutrophil lipocalin, a highly specific marker for acute exacerbation in cystic fibrosis, Eur Respir J 1999; 14: 1145-1149	
CF		HAN, W. K., et al., Kidney Injury Molecule-1(KIM-1): A novel biomarker for human renal proximal tubule injury; Kidney International, Vol. 62 (2002), pp. 237-244	
CF		ICHIMURA, T., et al., Kidney Injury Molecule-1 (KIM-1), a Putative Epithelial Cell Adhesion Molecule Containing a Novel Immunoglobulin Domain, is Up-regulated in Renal Cells after Injury, The Journal for Biological Chemistry, Vol. 273, No. 7, Issue of February 13, pp. 4135-4142, 1998	
CF		MALLBRIS, L., et al., Neutrophil gelatinase-associated lipocalin is a marker for dysregulated keratinocyte differentiation in human skin, Experimental Dermatology, Vol. 11, Issue 6 Page 584 - December 2002	Abstract
CF		MISHRA, J., et al, Amelioration of Ischemic Acute Renal Injury by Neutrophil Gelatinase-Associated Lipocalin; J. Am. Soc Nephrol 15:3073-3082, 2004	
CF		MISHRA, J., et al, Neutrophil gelatinase-associated lipocalin (NGAL) as a biomarker for acute renal injury after cardiac surgery, The Lancet, Vol. 365, April 2, 2005, pp. 1231-1238	
CF		MISHRA, J., et al., Neutrophil Gelatinase-Associated Lipocalin: A Novel Early Urinary Biomarker for	

CP	Cisplatin Nephrotoxicity, Am J Nephrol 2004; 24:207-315	
----	---	--

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CP		ODA, H., et al. Development and Evaluation of a Practical ELISA for human Urinary Lipocalin-Type Prostaglandin D. Synthase, Clinical Chemistry 48:9 1445-1453 (2002)		
		VINAYAK, S., et al., Prevalence of the K76T mutation in the pferl gene of Plasmodium falciparum amongst chloroquine responders in India, Acta Tropica, Volume 87, Issue 2, July 2003, pp. 287-293	Abstract	
CP		XU, S., Lipocalins as biochemical markers of disease, Biochimica et Biophysica Acta 1482 (2000) 298-307		

Examiner Signature	CP	Date Considered	5/18/07
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Attorney Docket No. CHM-015

COPENDING U.S. PATENT APPLICATION				
Examiner Initials*	Applicant(s)	Serial No.	Filing Date	Atty. Docket No.
CK	DEVARAJAN, et al.	11/096,113	03/31/2005	CHM-025M

Examiner Signature	Date Considered
<i>Chen</i>	5/18/07

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Application Number	10/811,130
Filing Date	March 26, 2004
First Named Inventor	Prasad DEVARAJAN et al.
Art Unit	1653
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Attorney Docket Number	CHM-015



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U.S. PATENT DOCUMENTS

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CH		US-	6,447,989	09/10/2002	Comper	
		US-				
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CH		LI YAN et al. The High Molecular Weight Urinary Matrix Metalloproteinase (MMP) Activity is a Complex of Gelatinase B/MMP-9 and Neutrophil Gelatinase-associated Lipocalin (NGAL), J. Biol. Chem., 05 October 2001, Vol. 276, No. 40, pages 37258-37265	
CH		MONIER et al., Gelatinase isoforms in urine from bladder cancer patients. Clinica Chimica Acta. September 2000, Vol. 299, (1-2), pages 11-23	
CH		ELNEIHOUM et al. Lukocyte Activation Detected by Increased Plasma Levels of Inflammatory Mediators in Patients with Ischemic Cerebrovascular Diseases. Stroke. (1996), Vol 27, pages 1734-1738	

Examiner
Signature

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Considered

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